

Provisional translation

The Food Safety Commission
Final decision on January 29, 2004

This English version of the Commission Decision is intended to be reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail. The Food Safety Commission of Japan (FSCJ) shall not be responsible for any consequence resulting from use of this English version.

Stance on the Safety Assessment of GM Plants Generated through Cross-Breeding

The safety assessment of genetically modified (GM) plants intended for food use has been conducted, mainly focusing on the equivalency of safety compared to the conventional counterpart.

Before FSCJ was established, the GM plants generated through conventional cross-breeding between the GM and non-GM plants has already been defined as “progeny cultivar through cross-breeding” by Ministry of Labour Health and Welfare (MHLW) in its Public Notice No. 233 (2000). GM plants are regarded as the safety confirmed GM plants when the following conditions are fulfilled.

- i) Properties newly acquired through recombinant DNA technique have not altered in progeny cultivar.
- ii) No cross-breeding between subspecies
- iii) Neither the dietary intake, edible part nor processing methods, etc. is changed

On the basis of the previously approved assessments on GM plants and the safety of GM plants defined by MHLW in its Notice, FSCJ summarized the approach on the safety assessment of GM plants produced by cross breeding as follows.

« Categorization of parental GM plants »

Parental GM plants are categorized into the following three types according to the introduced traits.

- 1) Type I: GM plants with traits, such as herbicide tolerance, insect resistance, or virus resistance, in which no effects are observed on the metabolisms of the host plants by the inserted genes.

2) Type II: GM plants with traits, such as increased amount of nutritional components, or altered content of cell wall components, in which metabolic pathways of the host plants are altered by the inserted genes.

3) Type III: GM plants with “de novo generated substances,” in which new substances are produced by the inserted genes, using metabolites of the host plants.

« **Necessity for the safety assessment of GM plants generated through cross-breeding** »

(1) GM plants generated through the following crossings;

- [Type I, Type II, or Type III] × non-GM plants
- Type I × Type I

Only in the following cases, the safety assessment of the GM plants needs to be conducted for the time being;

- In the case where the GM plant is generated through crossing among different subspecies or higher taxonomic than subspecies;

- In the case where the change in the amount of dietary intake, or edible part, or processing methods etc., is intended.

(2) GM plants generated through the following crossings;

- Type I × Type II
- Type I × Type III

The safety assessment of the GM plants needs to be conducted for the time being.

(3) GM plants generated through the following crossings;

- Type II × Type II
- Type II × Type III
- Type III × Type III

The safety assessment of the GM plants needs to be conducted.